# SUMMARY OF THE REGULATORY COORDINATION COMMITTEE MEETING MAY 5, 1999

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Wednesday, May 5, 1999, at 4 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Dr. Carl Kircher of the Florida Department of Health. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purposes of the meeting were to elect a chair, to approve committee minutes from the Fourth Interim NELAC meeting, to approve nominees to fill vacancies on the committee, to review the proposed revised International Standardization Organization (ISO) 17025 draft document, to discuss the availability of the April 1999 United States Environmental Protection Agency (EPA) Regulatory Agenda on the Internet, to discuss proposed revisions to spreadsheets and other documents currently posted on the NELAC Internet site, to approve a short version of the Model Administrative Rules for posting on the NELAC Internet site, to approve posting the October 1998 USEPA Regulatory Agenda on the NELAC Internet site, and to update committee members on NELAC Board of Directors (BoD) business.*

## INTRODUCTION

Following a call to order, Dr. Kircher referred participants to the agenda that had been distributed electronically prior to the meeting. Included with the agenda were six file attachments constituting topics of committee discussion. Some participants were unable to open one or more of the file attachments. In response, Dr. Kircher offered to transmit the six attached files again, each attached to a separate e-mail message, to ensure that all committee members would be able to review the documents. He deferred election of a committee chair since there was not a quorum of voting members in attendance.

## PROSPECTIVE MEMBERS

Discussion turned to membership issues. Dr. Kircher noted that two voting members (Mr. Alva Smith, U.S. EPA/Region 6, and Dr. Harry Otto, State of Delaware) are rotating off the Regulatory Coordination Committee. Dr. Kircher presented two nominees to replace them on the committee and noted that he had recently been in contact with one of them. Both nominees met with unanimous participant approval. Dr. Kircher also noted that one contributing member (Mr. David MacLean, independent consultant) is rotating off the Regulatory Coordination Committee. Mr. MacLean's replacement (Mr. Eddie Clemons, Xenco Laboratories) has already been confirmed.

## REVIEW OF ISO 17025 DRAFT

As discussed at the Fourth Interim NELAC meeting, ISO Guide 25 for the "General Requirements for the Competence of Testing and Calibration Laboratories" has been proposed for revision as ISO draft document 17025. Since ISO Guide 25 forms the crux of NELAC Standard Chapter 5 (Quality Systems), its revision may strongly impact laboratory accreditation. For this reason, the Regulatory Coordination Committee will prepare a report to the Quality Systems

Committee to inform them of the revisions. Dr. Kircher referred participants to a draft report distributed as an e-mail attachment prior to the meeting. The report enumerates and discusses six major changes reflected in ISO 17025, as summarized below:

- Alignment of sections to be more consistent with ISO 9001 and ISO 9002.
- Increased emphasis on laboratories to assess measurement uncertainties and to control result variabilities.
- Inclusion of sampling requirements to go with calibration and testing requirements.
- Inclusion of validation standards for performance-based measurement systems (PBMS).
- Allowances for expressing opinions and interpretations in test reports.
- Elimination of the detailed list of what laboratories must have in their quality manuals.

The report also undertakes a thorough cross-reference comparison of ISO Guide 25 to ISO 17025. After moderate discussion of the report, Dr. Kircher encouraged participants to review it at their earliest convenience and to submit comments and revisions. Although there is no set deadline for review, comments received prior to May 31, 1999, will be incorporated into a version to be presented at the upcoming Fifth Annual NELAC meeting in Saratoga Springs, NY.

**REVIEW OF DOCUMENTS TO BE POSTED ON THE NELAC INTERNET SITE**

Participants then turned their attention to several other documents distributed prior to the meeting as e-mail attachments. The first to receive their attention were four Microsoft® Excel spreadsheets comprising a compendium of U.S. EPA reference methods, performance methods, and analytes for Clean Air Act chemistry, field measurements, Safe Drinking Water Act chemistry, and Clean Water Act Chemistry. The Clean Air Act chemistry and field measurements spreadsheets are being posted on the NELAC Internet site for the first time. Although the Safe Drinking Water Act chemistry and Clean Water Act chemistry spreadsheets have already been posted on the NELAC Internet site, they are being revised to reflect new regulations promulgated by U.S. EPA. Dr. Kircher noted that the Clean Water Act revisions consist of methods and analytes for pharmaceutical industry effluent pre-treatment standards. Dr. Kircher again urged participants to review the documents and requested comments by May 14, 1999.

The last document that participants reviewed was a shortened version of the Model Administrative Rules already posted on the NELAC Internet site. The Model Administrative Rules currently posted on the NELAC Internet site consist of a 66-page document that references Code of Federal Regulations (CFR) methods, regulations, and documents containing the methods. It includes certification requirements and blanks for states to add supplemental information, such as fees or supplemental certification requirements. Although useful, this 66-page document may be considered bulky and complex. For this reason, a shorter version that allows a state to adopt NELAC fully by reference was developed. Dr. Kircher requested comments on this document by May 14, 1999.

## EPA REGULATORY AGENDA

Dr. Kircher noted that he has received no comments on the October 1998 Regulatory Agenda discussed at the Fourth Interim meeting. There being no committee objections, it will be submitted for posting on the NELAC Internet site. He also noted that the April 1999 Regulatory Agenda is now available on the Internet at *http://ciir.cs.umass.edu/ua*. Dr. Kircher solicited a volunteer to access the agenda and highlight items pertinent to laboratory accreditation for inclusion in a format similar to that presented at the Fourth Interim meeting. He stated that he would need this document by June 15, 1999, in order to present it at the Fifth Annual meeting. Participants were hesitant to undertake the task because they were uncertain as to what it would entail. Ms. Ilona Taunton requested that Dr. Kircher e-mail the October 1998 agenda to her as an attachment so that she could see the finished product. She will consider the assignment.

## NELAC BOARD OF DIRECTORS UPDATE

Having participated in the April 2, 1999, NELAC BoD teleconference, Dr. Kircher updated Regulatory Coordination participants on the following issues under consideration by the board:

**Tribal Nations Issue** - The Regulatory Coordination Committee is on record as having stated that there is nothing in the NELAC Constitution and By-Laws to prevent Native American Tribal Nations from becoming voting members of NELAC as Accrediting Authorities. Following committee discussion of this issue at the Fourth Interim meeting, Dr. Kircher sent a letter to Ms. Pauline Bouchard, chair of the Program Policy and Structure Committee, and Ms. Irene Ronning, chair of the Membership and Outreach Committee. They referred the matter to the BoD.

**ELAB Recommendations on PBMS** - ELAB has identified six critical elements and nine recommended elements important to PBMS, and what should be done to implement them.

Upon request from a meeting participant, Dr. Kircher agreed to send a copy of these recommendations to participants via U.S. Mail.

**Scope of Accreditation** - The BoD is considering a minimum scope of accreditation to be offered under NELAC. This would consist of a minimum set of analytes and methods for accreditation. The issue is also of interest to the Database *Ad Hoc* Committee.

After moderate discussion of scope of accreditation, the question arose of whether it would be appropriate for the Regulatory Coordination Committee to prepare a list of programs, methods, and analytes covered by NELAC. It was decided that this would be an appropriate agenda item for the Fifth Annual meeting. Dr. Kircher stated that he would contact the board to confirm that this item is appropriate to the committee charge.

**Other ELAB Recommendations** - The BoD is interested in following through on ELAB recommendations. One such recommendation is that NELAC reach out to and assist small laboratories by offering links on the NELAC Internet site to other Internet sites that offer model standard operating procedures (SOP's), case histories, model quality manuals, etc. This issue has been identified as pertinent to the Regulatory Coordination Committee.

Dr. Kircher noted that he has been advised that it is not allowable to link to non-governmental Internet sites from a governmental site. A participant suggested that it would be appropriate for other groups to offer this service, and mentioned the American Council of Independent Laboratories (ACIL) as one potential candidate.

**Transition Committee Concerns** - The primary Transition Committee concerns are the timetables for approval of accrediting authorities and NELAP accreditation of testing laboratories, and the timetable for when NELAC standards voted upon in July take effect.

In response to questions from teleconference participants, Dr. Kircher explained the timetables suggested at the Fourth Interim meeting. The first wave of accrediting authorities will be approved in June or July of 1999. In the following year, testing laboratories may apply for NELAC accreditation. During that year, the testing laboratories must analyze proficiency testing (PT) samples and undergo an on-site assessment. NELAP reaffirmed that approved laboratories may not claim NELAC accreditation (by referencing NELAC on company letterhead, for example) until the time that all laboratories will be simultaneously announced (goal is July 2000). Dr. Kircher noted that the BoD has stated that a testing laboratory will not be accredited until it has been audited against the NELAC standards. It has been recommended that NELAC standards voted upon by the conference in July take effect in January of the next year.

**Frequently Asked Questions (FAQ)** - The BoD and the Membership and Outreach Committee are actively recruiting individuals to provide FAQ about NELAC.

**Comments on NELAC Standards** - The BoD has received comments from several organizations, such as the Department of Defense and the Illinois EPA. These comments will be forwarded to the appropriate committees.

**NEW BUSINESS/CONCLUSION**

Dr. Kircher asked participants if they had any questions about the annual meeting agenda. None were offered. Participants did have questions, however, about the continued funding of NELAC by EPA. In response, Dr. Kircher referenced a recent EPA/Region 4 presentation that indicated no intent to withdraw funding from NELAC. This led to some discussion of the investment necessary for a laboratory to obtain and maintain NELAC accreditation, and the need for a cost-benefit analysis. It was noted that a cost-benefit analysis document is available on the Regulatory Coordination Committee portion of the NELAC Internet site. Dr. Kircher asked for presentation of any new business, and none was presented for consideration. The allotted teleconference time having expired, the committee meeting was adjourned at 5:30 p.m. EDT.

**Attachment A**

## ACTION ITEMS
## REGULATORY COORDINATION COMMITTEE TELECONFERENCE
## MAY 5, 1999

| Item No. | Action | Date to be Completed |
|---|---|---|
| 1. | Dr. Kircher will e-mail the following six files to committee members, each as an attachment to a separate e-mail message:<br><br>1) Shortened Version of Model Administrative Rules (Microsoft® Word file)<br>2) Clean Air Act chemistry spreadsheet (Microsoft® Excel file)<br>3) Field Measurements spreadsheet (Microsoft® Excel file)<br>4) Safe Drinking Water Act chemistry spreadsheet (Microsoft® Excel file)<br>5) Clean Water Act chemistry spreadsheet (Microsoft® Excel file)<br>6) Report on ISO 17025 draft document (Microsoft® Word file) | Immediately |
| 2. | Committee members will review shortened version of Model Administrative Rule and submit comments to Dr. Kircher. | May 14, 1999 |
| 3. | Committee members will review each method-analyte spreadsheet and submit comments to Dr. Kircher. | May 14, 1999 |
| 4. | Committee members will review report on ISO 17025 and submit comments to Dr. Kircher. | May 31, 1999 (for incorporation into version to be presented at NELAC V) |
| 5. | Dr. Kircher will e-mail October 1998 EPA Regulatory Agenda as presented at NELAC IVi to Ilona Taunton so that she may use it as a template if she prepares April 1999 EPA Regulatory Agenda in similar format. | Immediately |
| 6. | Committee will decide on individual who will access April 1999 EPA Regulatory Agenda, identify items pertinent to laboratory accreditation, and prepare for presentation at NELAC V. | June 15, 1999 |
| 7. | Dr. Kircher will contact NELAC BoD to confirm that preparation of minimum set of analytes and methods to establish minimum scope of NELAC accreditation is appropriate to Regulatory Coordination Committee charge. | Immediately |

**Attachment B**

**PARTICIPANTS**
**REGULATORY COORDINATION COMMITTEE TELECONFERENCE**
**MAY 5, 1999**

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